

REMARKS

Amendments to the Claims

Claims 1-3, 5-9, 11 are pending. Claims 4, 10, 12-23 are cancelled. The present claims are identical to the claims previously presented with our response dated November 20, 2008.

No new matter has been added.

Background to the present response

In a telephone interview with the Examiner held on February 10, 2009, Applicant's attorney summarised the prosecution history and re-emphasised that Khuri does not disclose diagnosing a pathological condition. The Applicant is appreciative of the Examiner's confirmation that these arguments are persuasive, subject to conducting a further search and review within the Office, and subject to the Applicant filing a written response. Applicant's written response is as follows:

Rejection of claims 1-3, 5-9 and 11 under 35 USC 102(e)

The Examiner expressed the view that claims 1-3, 5-9 and 11 were anticipated by US 6,567,679 (Khuri).

The Examiner stated that Khuri discloses a method of diagnosing a pathological condition of a patient's body tissue.

In contrast, as explained in our response dated February 1, 2008, the Applicant respectfully submits that Khuri does not teach a method of diagnosing a pathological condition of a patient's body tissue.

Khuri is concerned with monitoring pH in a heart, during cardiac surgery. As explained in column 1, lines 22 to 30, during the cardiac surgery, the aorta is clamped, which deprives the

myocardium of its blood and nutrient supply. This is done because it is not easy to perform such surgery on a beating heart.

Stopping the blood supply will cause acidosis/ischaemia, so it is not desirable to keep the blood supply cut off for too long. On the other hand, the surgeon wants to have as much time as possible to operate, without damaging the patient. Therefore, Khuri describes how the pH of the myocardium is monitored to determine the degree of tissue acidosis and thus the onset of myocardial ischaemia. Hence, as described on column 1, lines 57 to 59, the safe period of oxygen deprivation can be extended.

Therefore, in Khuri's method, the cause of this acute ischaemia is the surgery itself. This ischaemia did not exist before the surgery, but was instead caused by the surgical act of clamping the aorta, cutting of the blood supply. Hence, the ischaemia in this example is not caused by a disease or injury, and is therefore not a pathological condition.

In contrast, the present invention is concerned with a method of diagnosing a pathological condition by using a pH sensor that is inserted into a tissue.

Hence, claim 1 is novel over Khuri, because Khuri does not disclose:

- a) a method of diagnosing a pathological condition of a patient's body tissue; or
- b) using a pH measurement to diagnose the pathological condition.

#### Non-obviousness over Khuri

Claim 1 is directed to a completely different technical field - of diagnosing a pathological condition, rather than the field of keeping a heart healthy during surgery. One such pathological condition is compartment syndrome, which is described on page 2, line 11 to page 3, line 8 of the application as filed. To monitor compartment syndrome, it is known to use pressure monitoring (page 3, lines 10-13). The non-obviousness of the present invention lies in the use of a new monitoring method - pH monitoring - instead of the known pressure monitoring method. This is not merely an obvious modification, because compartment syndrome is defined as "a condition

in which increased pressure within a limited space compromises the circulation and function of tissues in that space" (see page 2, lines 16 to 19 of the application as filed). Hence, when trying to identify a condition defined by increased pressure, it may be obvious to monitor pressure. However, it is not at all obvious to monitor an entirely different parameter, such as pH, or to realise that pH monitoring may give more reliable results.

The person of ordinary skill in the art, looking to improve a method of diagnosing a pathological condition such as acute compartment syndrome, would not turn to Khuri, which is in the different technical field of keeping a heart healthy during surgery, whilst a blood supply is deliberately cut off.

Even if the person of ordinary skill in the art did turn to Khuri, he would learn that if you are wishing to prevent tissue acidosis during a surgical operation, pH can be monitored. However, this does not automatically lead him, without any exercise of inventive activity, to decide to use pH monitoring in the completely different field of diagnosis of pathological conditions, particularly when some such conditions, e.g. compartment syndrome, are defined in terms of an excess of pressure, and not pH. Thus, monitoring of pH in such conditions is actually counter-intuitive, when directly monitoring the parameter which actually defines the condition (pressure) is already known.

Hence, claim 1 is non-obvious over Khuri.

#### Claims 2, 3, 5 to 9 and 11

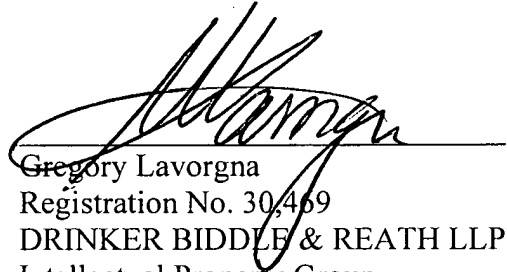
Claims 2, 3, 5 to 9 and 11 are all dependent on claim 1, and thus are also novel and non-obvious, at least by virtue of this dependency.

#### Request for Allowance

It is thus believed that the application is now allowable and notification to this effect is earnestly solicited. Should the Examiner have any questions or comments regarding Applicants'

amendments or response, he is asked to contact Applicants' undersigned representative at (215) 988.3309. Please direct all correspondence to the below-listed address. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Lavorgna', is written over a horizontal line.

Gregory Lavorgna  
Registration No. 30,469  
DRINKER BIDDLE & REATH LLP  
Intellectual Property Group  
One Logan Square  
18<sup>th</sup> and Cherry Streets  
Philadelphia, PA 19103-6996  
Tel: (215) 988.3309  
Fax: (215) 988.2757